UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,781	10/10/2001	Michael G. Kahn	FSTK 1004-1	8124

22470 7590 03/07/2007
HAYNES BEFFEL & WOLFELD LLP
P O BOX 366
HALF MOON BAY, CA 94019

EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	PAPER NUMBER
3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/974,781	KAHN ET AL.	
	Examiner	Art Unit	
	Dilek B. Cobanoglu	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/11/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to Request for Continued Examination (RCE) received on 12/20/2006. Claims 1-51 are still pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6-22 are rejected under 35 U.S.C. 102(e) as being unpatentable by Briegs et al. (hereinafter Briegs) (U.S. Patent No. 7,054,823 B1).

A. As per claim 1, Briegs discloses a method for evaluating a clinical trial protocol specification, comprising the steps of:

i. encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including substeps of writing, into protocol specification objects of said database, specifications of protocol events that said protocol specifies to occur during execution of said protocol, and, relationships that said protocol specifies among said protocol events (Briegs; col. 6, lines 19-23, col. 9, lines 11-21);

ii. during said step of encoding workflow tasks but not during any of said substeps, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter with less precision than is required by a slot in said database for encoding the parameter, or said protocol specification contains at least two such parameter specifications which are in conflict (Briegs; col. 13, lines 2-10 and lines 21-54);

iii. encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object (Briegs; col. 13, lines 21-54); and

iv. in dependence upon protocol specification objects in said database, before execution of said clinical trial protocol, displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular protocol specification object has said operational uncertainty associated therewith (Briegs; col. 18, lines 10-21).

B. As per claim 2, Briegs discloses a method according to claim 1, wherein said database is an object-oriented database (Briegs; col. 6, lines 19-23, lines 33-55).

C. As per claim 3, Briegs discloses a method according to claim 1, wherein said protocol specification objects include protocol event objects describing protocol events (Briegs; col. 9, lines 11-21), and temporal constraint objects describing temporal constraints among said protocol event objects (Briegs; col. 13, lines 2-10).

D. As per claim 6, Briegs discloses a method according to claim 1, wherein said operational uncertainty comprises said protocol specification containing at least two parameter specifications which are in conflict (Briegs; col. 13, lines 21-54).

E. As per claim 7, Briegs discloses a method according to claim 1, a method according to claim 1; wherein said operational uncertainty comprises said protocol specification specifying a parameter with less precision than is required by a slot in said database (Briegs; col. 13, lines 21-54).

F. As per claim 8, Briegs discloses a method according to claim 1, wherein said operational uncertainty comprises an omitted parameter in said protocol specification (Briegs; col. 13, lines 21-54).

G. As per claim 9, Briegs discloses a method according to claim 1, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events (Briegs; col. 13, lines 21-54).

H. As per claims 10-22 and 23-33, they are article of manufacture claims, which repeats the same limitations of claims 1-3, 6-9, the corresponding method claims, as a collection of executable instructions stored on machine readable media as opposed to a series of process steps. Since the teachings of Briegs disclose the

underlying process steps that constitute the method of claims 1-3, 6-9, it is respectfully submitted that they likewise disclose the executable instructions that perform the steps as well. As such, the limitations of claims 10-22 and 23-33, are rejected for the same reasons given above for claim 1-3, 6-9.

l. As per claim 34, Briegs discloses a method for evaluating a clinical trial protocol specification, comprising the steps of:

i. encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, said step of encoding including substeps of writing data from said protocol specification into said database (Briegs; col. 6, lines 19-23, col. 9, lines 11-21), said database being structured according to a predetermined model, said model including slots predefined for describing respective aspects of protocol events that a protocol can specify to occur during execution of the protocol, said model further including slots predefined for describing temporal relationships that a protocol can specify among such protocol events, said slots predefined for describing temporal relationships including slots predefined for describing amounts of time that a protocol specifies are to elapse between two or more protocol events (Briegs; col. 12, lines 57-64, col. 13, lines 2-10); and

ii. during said step of encoding, but not during any of said substeps of writing, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said

protocol specification fails to specify an amount of time that is to elapse between two or more protocol events, or said protocol specification specifies such an amount of time with less precision than is required by a slot in said database, or said protocol specification specifies such an amount of time in conflict with another parameter specified in said protocol specification (Briegs; col. 7, lines 30-32, col. 17, lines 3-15).

J. As per claim 35, Briegs discloses a method according to claim 34, further comprising the step of displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular amount of time has an operational uncertainty associated therewith (Briegs; col. 18, lines 10-21).

K. As per claim 36, Briegs discloses a method according to claim 36, wherein said predetermined model comprises a predetermined object class structure and said slots are organized into protocol specification objects defined by said object class structure (Briegs; col. 17, lines 3-15).

L. As per claim 37, Briegs discloses a method according to claim 36, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among events described in said protocol event objects, each of said temporal constraint objects including at least one slot for identifying an amount of time allowed between two or more protocol events (Briegs; col. 17, lines 3-15).

M. As per claim 38, Briegs discloses a method according to claim 37, further comprising the steps of:

i. instantiating a disambiguation protocol specification object defined according to said object class structure describing said operational uncertainty (Briegs; col. 13, lines 21-54); and

ii. associating said disambiguation protocol specification object with one of said constraint objects (Briegs; col. 13, lines 21-54).

N. As per claim 39, Briegs discloses a method according to claim 34, wherein said operational uncertainty comprises said protocol specification specifying a particular amount of time in conflict with another parameter specified in said protocol specification (Briegs; col. 13, lines 21-25, col. 17, lines 9-15).

O. As per claim 40, Briegs discloses a method according to claim 34, wherein said operational uncertainty comprises said protocol specification specifying a particular amount of time with less precision than is required by a slot in said database.

P. As per claim 41, Briegs discloses a method according to claim 34, wherein said operational uncertainty comprises omission a particular amount of time from said protocol specification (Briegs; col. 13, lines 21-25, col. 17, lines 9-15).

Q. Claims 42 and 45 repeat the same limitations as claim 1 and 2, therefore are rejected for the same reasons given in the rejection of claims 1 and 2 above, and incorporated hereinwith.

R. As per claim 43, Briegs discloses a method according to claim 42, further comprising the steps of:

i. encoding into a protocol disambiguation object said indication that said operational uncertainty exists (Briegs; col. 13, lines 21-54); and

ii. associating said protocol disambiguation object with said particular protocol specification objects in said database (Briegs; col. 13, lines 21-54).

S. As per claim 44, Briegs discloses a method according to claim 43, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among protocol events described in said protocol event objects (Briegs; col. 13, lines 21-54), and wherein said step of associating comprises the step of associating said protocol disambiguation object with one of said protocol event objects or one of said temporal constraint objects in said database (Briegs; col. 13, lines 55-67).

T. As per claim 46, Briegs discloses a method according to claim 42, further comprising the step, prior to said step of outputting, of sorting a list of said operational uncertainties identified in said protocol and encoded into said database (Briegs; col. 14, lines 1-9).

U. As per claim 47, Briegs discloses a method according to claim 42, wherein said step of outputting comprises the step of outputting in tabular form the

operational uncertainties identified in said protocol and encoded into said database (Briegs; col. 43, lines 42-58).

V. As per claim 48, Briegs discloses a method according to claim 42, wherein said operational uncertainty comprises said protocol specification containing at least two parameter specifications which are in conflict (Briegs; col. 13, lines 21-54).

W. As per claim 49, Briegs discloses a method according to claim 42, wherein said operational uncertainty comprises said protocol specification specifying a parameter with less precision than is required by a slot in said database (Briegs; col. 13, lines 21-54).

X. As per claim 50, Briegs discloses a method according to claim 42, wherein said operational uncertainty comprises an omitted parameter in said protocol specification (Briegs; col. 13, lines 21-54).

Y. As per claim 51, Briegs discloses a method according to claim 42, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events specification (Briegs; col. 13, lines 21-54).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briegs et al. (hereinafter Briegs) (U.S. Patent No. 7,054,823 B1) in view of Friedman (U.S. Patent No. 6,055,494).

A. As per claims 4 and 5, Briegs discloses a method according to claims 1 and 3.

Briegs fails to expressly teach displaying each protocol specification objects in a color, which differs whether an operational uncertainty is associated therewith. However, this feature is well known in the art, as evidenced by Freidman.

In particular, Freidman discloses displaying each protocol specification objects in a color, which differs whether an operational uncertainty is associated therewith (Freidman; col. 1, lines 56-58, Freidman; col. 4 lines 9-13).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation disclosed by Friedman with the motivation of produce error messages (Freidman; col. 3, lines 58-63).

Response to Arguments

6. Applicant's arguments with respect to claims 1-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not used prior art teach Research data collection and analysis 20020016530, Integrated disease information system 6108635 A, Interpolative method and system for producing medical charts and monitoring and recording patient conditions 6081809 A, Method and system for interactive prescription and distribution of prescriptions in conducting clinical studies 5991731 A, Research data collection and analysis 6196970 B1, Method and apparatus for electronically accessing and distributing personal health care information and services in hospitals and homes 5867821 A, Systems, methods and computer program products for guiding the selection of therapeutic treatment regimens 6081786 A, Method for entering information into an electronic patient chart, and protocol auto-negative capabilities 5812984 A, Computed medical file and chart system 5812983 A, Method and system for dispensing, tracking and managing pharmaceutical trial products 5832449 A.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC
DBC
Art Unit 3626
02/26/2007

Carolyn Bleck
Patent Examiner-3626
3/2/07